ACUTE ORAL TOXICITY STUDY IN RATS - LIMIT TEST

TEST METHOD NO.: P203

STUDY NUMBER: 8820

SPONSOR: SYNTROLEUM CORPORATION

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TEST SUBSTANCE IDENTIFICATION: RDIL 0486

TEST SUBSTANCE DESCRIPTION: Clear colorless liquid

DATE RECEIVED: February 18, 2000

PSL REFERENCE NO.: E00218-1D

DATES OF TEST: February 23 - March 8, 2000

NOTEBOOK NO.: 00-05; pages 306-311

PURPOSE

To provide information on health hazards likely to arise from a short-term exposure to RDIL 0486 by the oral route.

2. PROCEDURE

A group of Sprague-Dawley derived, albino rats was received from Ace Animals, Inc., Boyertown, PA. The animals were singly housed in suspended stainless steel caging with mesh floors. Litter paper was placed beneath the cages and was changed at least three times per week. The animal room was temperature controlled and had a 12-hour light/dark cycle. The animals were fed Purina Rodent Chow #5012 and filtered tap water was supplied ad libitum by an automatic watering system.

Following acclimation to the laboratory, a group of animals was fasted for approximately 19 hours by removing feed from their cages. After the fasting period, ten rats (five male and five female) were selected for test based on health and initial bodyweights. Individual doses were calculated based on these bodyweights, taking into account the specific gravity (determined by PSL) of the test substance. Each animal received 5,000 mg/kg of the test substance by intubation using a stainless steel ball-tipped gavage needle attached to an appropriate syringe. After administration, each animal was returned to its designated cage. Feed was replaced approximately 3.5 hours after dosing.

The animals were observed for mortality, signs of gross toxicity and behavioral changes one hour postdosing and at least once daily for 14 days. Bodyweights were recorded prior to initiation and at termination (Day 14). Surviving animals were euthanized by CO₂ inhalation at termination,

RESULTS

Individual bodyweights, doses and mortalities are presented in Table 1. Cage-side observations are presented in Table 2.

All animals survived, gained weight and appeared active and healthy. There were no signs of gross toxicity, adverse pharmacologic effects or abnormal behavior.

4. CONCLUSION

The single dose acute oral LD₅₀ of RDIL 0486 is greater than 5,000 mg/kg of bodyweight.

SIGNATURES

RDIL 0486

We the undersigned declare that the method procedures used and raw data collected durin	s, results and data contained in this report faithfully reflect the g the study.
Daniel Merkel, B.S. Study Director	Date
Sandeep Cheema, B.S. Principal Toxicology Technician	Date
Frank Fielder, B.S.	Date

Quality Assurance Supervisor

TABLE 1: INDIVIDUAL BODYWEIGHTS AND DOSES

Animal No.	Sex	Bodyweight (g)		Dose
		Initial	Day 14	mL
3584	М	248	351	1.7
3585	M	238	345	1.6
3586	M	210	325	1.4
3587	M	262	357	1.7
3588	M	230	317	1.5
3589	F	155	221	1.0
3590	F	170	255	1.1
3591	F	176	251	1.2
3592	F	182	260	1.2
3593	F	179	249	1.2

Administered as received. Specific Gravity - 0.751 g/ml.

TABLE 2: INDIVIDUAL CAGE-SIDE OBSERVATIONS

Animal Number	Findings	Day of Occurrence
MALES		
3584-3588	Active and healthy	0-14
FEMALES		
3589-3593	Active and healthy	0-14